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EXAMINER	
NGUYEN, TUAN VAN	
ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,801	GARBE, JEAN-FRANCOIS	
	Examiner	Art Unit	
	TUAN V. NGUYEN	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. In previous Office action, claims 10-21 are pending in this present applicant and these claims were examined and rejected.

Response to Amendment

2. Applicant's arguments have been fully considered but they are not persuasive.
    a. Applicant argues neither Weadock nor Schulsinger et al. discloses or suggest "a series of transfixion pins ...radially encircling the cylinder" is incorrect. Weadock clearly discloses (Fig. 3) the plurality of bent staples 28 and 30 which are spaced around the periphery of the body structure 22 (col. 5, lines 32-34).
    b. Applicant argues neither Weadock nor Schulsinger et al. disclose "a mesh cylinder capable of radial expansion between a stable minimal-diameter configuration and a final after-expansion configuration that is also stable" is incorrect. Weadock clearly discloses that the anastomotic coupler 20 which includes a tubular shaped structure 22 which allow for radial expansion and forming a compliant annular body (col. 5, lines 20-25). According to the Merriam-Webster's Collegiate Dictionary, "stable" is defined as "designed so as to develop forces that restore the original condition when disturbed from a condition of equilibrium or steady motion". Weadock clearly discloses the device allows for radial expansion and

forming a compliant annular body (col. 5, lines 20-25), thus, Weadock discloses the limitation of "capable of radial expansion between a stable minimal-diameter configuration and a final after-expansion configuration that is also stable".

c. Applicant argues neither Weadock nor Schulsinger et al. disclose nor suggest "a mesh sleeve deformable by use of balloon catheter" is incorrect. Weadock clearly discloses that the anastomotic coupler 20 which includes a tubular shaped structure 22 which allow for radial expansion and forming a compliant annular body (col. 5, lines 20-25), Thus, Weadock discloses mesh sleeve that capable to be deformed or expanded by any mechanical devices which includes a balloon catheter.

d. Applicant argues that Schulsinger et al does not disclose or suggest "hemostasis is achieved at transfixion sites in the wall of the body duct created by the transfixion pins". Noting that Weadock's prosthesis is for repairing aortic aneurysms. It is old and well known in the art the fastening mechanism for affixing the prosthesis to the aorta must provides hemostasis to prevent the complication from loosing of blood in the vascular system, thus, the barbs 28 and 30 of Weadock's device capable to provide hemostasis. Further, Weadock as modified by Schulsinger et al. provides the advantage of reducing trauma to the tissue being penetrated as the trihedral-shaped tip creates a cleaner incision with less tearing of the tissue as suggested by Schulsinger et al. (see col. 2, lines 25-28).

e. With respect to the argument that lack of criticality is not a measure of the obviousness of the claim subject matter. Examiner contends that Weadock and Martin disclose the connector or sleeve capable to expand from a small initial diameter to a final diameter that larger than initial diameter for ease of facilitating delivering of the prosthesis to the implanted side via minimal invasive surgery. It would have been obvious to one having ordinary skill in the art to design the modified connector of Weadock to have a ratio of a final diameter to an initial diameter is greater than 2, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. **Claims 10 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weadock (U.S. 6,911,042) in view of Schulsinger et al (U.S. 5,897,572).**

6. Referring to claims 10 and 17, Kevin discloses (see Fig. 2 and 3) a prosthesis for the repair of thoracic or abdominal aortic aneurysm comprising: a graft 10 or prosthesis made from flexible material; a coupler 20 or mesh sleeve capable of radial expansion between a stable minimal-diameter configuration and a final after-expansion configuration that is also stable, the coupler includes a series of staples 28, 30 which are spaced around the periphery of the body structure 22 and the staples pierce through the graft 10 and the wall of the aorta 36 or transfixion pins proximate at ends 24, 26 (see col. 5, lines 5 to col. 6, line 60). Weadock discloses the invention substantially as claimed except for specifically disclosing the staple includes a circular base section extending to a trihedral-shaped end portion.

7. Still referring to claims 10 and 17, However, Schulsinger discloses (see Figs 1 and 7) a needle having a circular portion extending to a trihedral-shaped end portion thereby reducing trauma to the tissue being penetrated as the cutting edges 16 creates a cleaner incision with less tearing of the tissue (see col. 2, lines 25-28). Therefore, it would have been obvious to one of ordinary skill in the art to form the staple as disclosed by Schulsinger with the circular base and trihedral-shaped distal tip as disclosed by Shulsinger so that it too would have the same advantage.

8. **Claims 11-12 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weadock (U.S. 6,911,042) in view of Schulsinger et al (U.S. 5,897,572) as applied to claim 10 above and further in view of Martin (U.S. 5,397,355).**

9. Referring to **claims 11-12**, the modified device of Weadock discloses the invention substantially as claimed except for the coupler or mesh sleeve including diamond-shaped cutouts, each transfixation pin attached at each intersection of sides of the diamond-shaped cutouts. However, Martin discloses such an arrangement of the barbs on his endoluminal graft connector (see Fig. 5 and col. 1 to col.3). Apparently the plurality of barbs was used to allow the connector to expand with lesser force and to increase the security of the attachment of the connector and the vessel together (see Summary of the Invention). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate the design of diamond-shaped and location of the barbs as disclosed by Martin into the tubular structure as disclosed by Weadock and Schulsinger so that it too would have the same advantage.

10. Referring to **claim 13**, due to lack of criticality in the specification, expanding the sleeve to a final diameter which is greater than twice its initial diameter was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to expanding the sleeve to twice the diameter or just under twice the diameter. Noting that Weadock and Martin disclose the connector or sleeve capable to expand from a small initial diameter to a final diameter that

larger than initial diameter. It would have been obvious to one having ordinary skill in the art to design the modified connector of Weadock to have a ratio of a final diameter to an initial diameter is greater than 2, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

11. **Claims 14, 15 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weadock (U.S. 6,911,042) in view of Schulsinger et al (U.S. 5,897,572) and Martin (U.S. 5,397,355) as applied to claims 11 and 12 above and further in view of Derowe et al (U.S. 7,022,131).**

12. Referring to **claim 14**, the modified device of Weadock discloses the invention substantially as claimed except for the limitations in claim 14. However, Derowe discloses (see col. 60, lines 5-25) not all the spikes of his coupler of mesh sleeve have the same cross section and/or sharpness and/or tip shape and/or have different bending locations. Due to lack of criticality in the specification, the transfixion pins on each end of the sleeve are straight, and wherein the intermediate transfixion pins are slightly curved was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to the modified design of Weadock. It has been held that simple substitution of one known element for another to obtain predictable results is old and well in the art, therefore, it would have been obvious to one of ordinary skill in the art to try the design of the spikes as disclosed by Derowe into the modified device of Weadock.

13. Referring to **claims 15 and 21**, noting that Martin disclose the barbs positioned at an angle. Therefore, it would have been obvious to one having ordinary skill in the art to design the angle of the barbs of the modified connector of Weadock to have an angle of 5 degrees or a range of between 0 degrees and 10 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

14. **Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weadock (U.S. 6,911,042) in view of Schulsinger et al (U.S. 5,897,572) and Martin (U.S. 5,397,355) as applied to claims 11 and 12 above and further in view of Chobotov et al (US 2003/0120338).**

15. The modified device of Weadock discloses the invention substantially as claimed except for the length of each barb can vary within a single device. However, Chobotov discloses such a design (see page 6, paragraph 80). Apparently the design intended is so that the barb lengths can be of the appropriate length for the thickness of the multiple or single layers that it has to pierce through and to prevent the damage to the surrounding tissue juxtaposed t the anastomosis site. Therefore, it would have been obvious to one of ordinary skill in the art to incorporate the design of barbs as disclosed by Chobotov to the modified device of Weadock so that it to would have the same advantage.

16. **Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weadock (U.S. 6,911,042) in view of Schulsinger et al (U.S. 5,897,572), Martin**

(U.S. 5,397,355), and Chobotov et al (US 2003/0120338) as applied to claims 11 above and further in view of Duhaylongsod et al (U.S. 6,241,741).

17. Referring to **claims 19-20**, the modified device of Weadock discloses the invention substantially as claimed except for teaching the method of attaching the barbs to the device. However, Duhaylongsod discloses the barbs 36 are attached to the device by either soldering or gluing (see Fig. 1A and col. 4, lines 40-45). Therefore, it would have been obvious to use method of attaching the barbs to the device as disclosed by Duhaylongsod to the modified device as disclosed by Weadock because the aforementioned attaching methods are old and well known in the art. It has been held that choosing from a finite number of identified, predictable solution, with a reasonable expectation of success it is old and well known in the art.

18. **Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Golsteen et al (U.S. 5,941,908) in view of Weadock (U.S. 6,911,042) further in view of Schulsinger et al (U.S. 5,897,572) and further in view of Derowe et al (U.S. 7,022,131).**

19. Golsteen discloses (see Figs. 1-9) the method of performing end-to-end anastomosis of at least two body ducts substantially as claimed including the steps of intubing a first end of a prosthesis in an extremity of a body duct; setting in place a first connecting device by introducing an inflatable balloon catheter into the prosthesis; intubing a second end of the prosthesis of the prosthesis in a second body duct setting in place a second connecting device by the catheter introduced

into the prosthesis through an orifice in the prosthesis that is subsequently re-closed (see col. 2, lines 56-58; col. 4, lines 27-47). Golsteen also discloses a connecting device being a mesh sleeve that is capable of radial expansion between a minimal-diameter configuration and a stable expanded configuration (col. 2, lines 25-27; col. 4, lines 22-46). Golsteen discloses the invention substantially as claimed except for the first connecting device being set into place by introducing an inflatable balloon catheter into the prosthesis by inserting it through an end of the prosthesis and the connecting device further includes barbs that capable to pierce through the wall of a vessel.

20. However, the modified device of Weadock as described in paragraphs 6-8 above discloses the connecting device as claimed by the applicant. Therefore, it would have been obvious to one of ordinary skill in the art to use the modified connecting device as disclosed by Weadock to replace the connecting device as disclosed by Golsteen because this will eliminate the clip assembly 50, 52 thereby simplifying the procedure.

21. Derowe discloses (see Figs. 10A-10D) a method of end-to-end anastomosis substantially as claimed including the steps of intubing a first end of a prosthesis 152 includes spikes in the extremity of a body duct (see Fig. 10A), setting a connecting device in place by inflating a balloon catheter 156 (see Figs. 10B; col. 50, line 60 to col. 61, line 30). Due to lack of criticality in the specification about inserting the inflatable balloon catheter into the prosthesis through an end of the prosthesis was shown to solve no particular problem, serve no particular purpose,

and provide no additional benefit as opposed to inserting the catheter balloon into the prosthesis through an orifice on the prosthesis. Therefore, it would have been obvious to one of ordinary skill in the art to try the step of inserting the catheter balloon into the prosthesis through an end of the prosthesis as suggested by Derowe.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TUAN V. NGUYEN whose telephone number is (571)272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/T. V. N./
Examiner, Art Unit 3731

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731